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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,066	08/03/2001	Thierry Godel	20706	8721

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EXAMINER
PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,066

Applicant(s)

GODEL ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above claim(s) 9-34, 36-38, 41-43, 46-49, 51-68 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 35, 71-77 is/are rejected.
- 7) ☒ Claim(s) 3, 5-8, 39, 40, 44, 45, 50 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants' communication paper # 13 dated 8/22/03 is acknowledged.

1. Status of claims:

Applicants have cancelled claims 68, 70, amended claims 3,4, 35,44,45, and added new claims 71-77.

Based on the examination of this application, claims 9-34,36-38,41-43,46-49,51-68,70 are withdrawn from further consideration 37 CFR 1.142(b). MPEP 8098.02(c).

Therefore, the claims under consideration are the claims 1-8,35,39-40,44,45,50,69,71-77.

After further review and reconsideration, this application is found not ready for allowance as a single piece for reasons stated below.

2. Election/Restrictions

This application has been examined for the elected subject matter and species of claim 8. As already stated in the earlier office communication paper # 12 dated 6/11/03, the species has following meanings for various variables:

The elected species of Example 1 has following meanings for variables:
R1 = 6-membered saturated cyclic tertiary amine with one additional N as heteroatoms i.e.1, 4-diazine/piperazine) consisting of 2 N as heteroatoms and end N is (UN) substituted by -C (O)(R') wherein R' is lower alkyl which is substituted by C (O) R'' wherein R'' is H i.e. piperazine N is having a bridge = -CO-CH₂-OH;

(R) n = H;

m = zero;

R2 = alkyl or halogen;

X = -CO-N (R8)-;

R3/R3' = H;

R4/R4' = CF₃, and R4, R4'' are in 3,5-positions respectively compared to -X-CH₂-bridge;

R/R2 or R4/R4' = open & not forming a fusion with the ring.

Further search examination will involve additional search for the compounds as already stated in the earlier Office action, and this will be time consuming and burdensome to examiner.

The restriction/election is considered proper, and is now made FINAL.

Priority

3. The claim for foreign priority date 8/8/2000 cannot be granted for the instant U.S. Application Sr. No. 09922066 filed 8/3/2001, because the instant claims do not recite the same subject matter as claimed in the EPO 00117003 filed 8/8/2000.

R1, R2, R', R'' variables (where applicable) of instant claims 1, 2,3,4, 35,71,72,73, 76 are recited in a different way than the application, EPO00117003 filed 8/8/2000.

The differences are as:

- The variable R2 of phenyl ring is fixed as 2-position or ortho. The instant claims recite R1 as floating, and therefore, it can occupy any one of the 5 free positions as recited;
- The variable R1 meaning(s) are different e.g. the option k) in the instant claims (where applicable) recite additional subject matter other than -SR6, -S (O) R6, or -S (O) 2R6;
- The instant variable R1 recites option m). as: "aromatic heterocycle" which is not the same as the specification and claims in the EPO00117003 i.e. heteroaryl;

- The instant variable R1 recites option n). as: "non-aromatic heterocycle" which is not same as the specification and claims in the EPO00117003 i.e. saturated cyclic tertiary amine;
- The instant variables R'/R" are recited as: "hydroxy" which is not the same as the specification and claims in the EPO00117003.

This will raise additional issues under 35 U.S.C. 112 Para one and second, because the subject matter as now presented consists of addition of new matter in the claims.

Therefore, the priority will be considered as the date of filing of instant U.S. Application Sr. # 09922066, which is 8/3/2001.

Double Patenting

4. Applicants have filed TD as communication paper # 14 dated 8/22/03 for the U.S.P. 6297375. The same has been considered proper and has been recorded.

Therefore, the DP rejections are now withdrawn.

Claim Rejections - 35 USC § 102

5. Applicants, arguments, remarks together with cancellation and amendments of claims have been considered, and found persuasive for withdrawal of rejections made under 35 U.S.C. 102(b). Applicants have pointed out that the instant claims as presented now differ from the ref. '123 by having a fully unsaturated aromatic ring with 3 double bonds and not a single double bond. Therefore the rejections are now withdrawn.

Claim Rejections - 35 USC § 112

6. Applicants' cancellation of claim 68 makes the rejections made under 35 U.S.C. 112 paragraph first moot.

New Rejections/Objections:

Claim Objections

7. Claims 9-34,36-38,41-43,46-49,51-67 are objected because they consist of non-elected subject matter, which is withdrawn from further consideration.
8. The amendment filed as paper # 13 dated 8/22/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

Claims 71-77 don't recite the subject matter as claimed in the priority document, EPO 00117003, filed 8/8/2000. Same reasons apply as already discussed in section 3. "Priority" above.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2,4, 35,71-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

(A). Claims 1, 2, 4, 35, 71, 72, 73, 76 recite (where applicable) terms: "aromatic heterocycle, non-aromatic heterocycle". These terms are indefinite because the claims do not exactly and definitely represent the rings with exact number of heteroatoms(s), the exact point of attachment to the carbon atom of the core, and the nature of non-aromatic where applicable.

(B). Claims 1, 2, 4, 35, 71, 72, 73, and 76 (where applicable) recite the terms: "aryl". This is not acceptable. See *In re Sus et al.*, 135 USPQ 301; *In re Lund et al.*, 153 USPQ 625.

(C). Claims 1, 2, 4, 35, 71, 72, 73, 76 (where applicable) recite the terms: "containing, comprising". These are unacceptable because they do not represent the exact and definite meanings for the variables.

The use of the term comprising for the compound claims 4, 74, 75 leaves the claims open for the involvement of many more elements than those positively recited. *Ex parte Gottzein et al.* 168 U.S.P.Q. 176 (PTOP Bd. App. 1969).

(D). Claim 3 recites the variable « R », but the Formula IA does not show R component. Correction is required.

(E). Claims 77 is rejected because it is dependent on rejected claim(s).

Conclusion

Allowable Subject Matter

10. Claims 3, 5-8, 39, 40, 44, 45, 50, 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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11. Claim 2 related to compounds of Formula I wherein R1, R2, R, X, R3/R3', R4/R4'', R4/R4', R/R2 have the meanings as clarified in Restriction/election above, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and other rejections/objections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: (1). Applicants have provided Declaration under 37 C.F.R. 1.132 as paper # 10 dated 4/29/03 related to 35 U.S.C. 102(e) rejections against U.S.P. 6297375.

(2). Applicants have provided TD as paper # 14 dated 8/22/03 for DP rejections against U.S.P. 6297375.

(3). The closest prior art reference Yanagisawa et al (WO 98211185) teaches Arylureas or arylmethyl carbamoyl derivatives with a core: "6-position occupied by R4-4-position occupied by R3/phenyl-3-position occupied by NH or CH2-CO-NH- CH (R1)(R2)-pyridine wherein R4 is halogen or pyridine, piperidine, morpholine, R1/R2 are H, or alkyl or heteroaryl.

(4). The ref. '185 does not indicate or suggest to arrive at the instant compounds with a core: "6-position occupied by R1- 4-position occupied by phenyl substituted by methyl halogen etc. in 2' position-3-position occupied by-CO-N (R8)-CH (R3/R3'-Phenyl substituted by -(R4) n and R4' wherein R8, R3, R3' are H or alkyl, R4/R4' are H, alkyl, CF3, alkoxy.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.

The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.



Sudhaker B. Patel, D.Sc.Tech.
September 15, 2003.



MUKUND SHAH
SUPERVISORY PATENT
EXAMINER
ART UNIT 1624